

ABSTRACT

[000164] The present invention relates to analytical methods for detecting, identifying characterizing, purifying, obtaining structural information on, qualifying, screening, separating, fractionating and/or quantifying a Selective Androgen Receptor Modulator (SARM) compound in a sample, by obtaining a sample, and detecting the presence and/or concentration of a SARM compound in the sample. The methods of the present invention are highly robust, sensitive, specific, reliable, validated, validatable and reproducible assays that are of great commercial potential and value. The SARM compounds, either alone or as a composition, are useful for a) male contraception; b) treatment of a variety of hormone-related conditions, for example conditions associated with Androgen Decline in Aging Male (ADAM), such as fatigue, depression, decreased libido, sexual dysfunction, erectile dysfunction, hypogonadism, osteoporosis, hair loss, anemia, obesity, sarcopenia, osteopenia, osteoporosis, benign prostate hyperplasia, alterations in mood and cognition and prostate cancer; c) treatment of conditions associated with Androgen Decline in Female (ADIF), such as sexual dysfunction, decreased sexual libido, hypogonadism, sarcopenia, osteopenia, osteoporosis, alterations in cognition and mood, depression, anemia, hair loss, obesity, endometriosis, breast cancer, uterine cancer and ovarian cancer; d) treatment and/or prevention of acute and/or chronic muscular wasting conditions; e) preventing and/or treating dry eye conditions; f) oral androgen replacement therapy; and/or g) decreasing the incidence of, halting or causing a regression of prostate cancer. The development of a rapid, specific and sensitive assay for detection, identification and quantification of SARMS is of great value, allows better clinical evaluation and practice for a patient, is useful to monitor and reduce incidence of off-label use by athletes and others, offers important tools to investigate forensic and overdose situations, is useful in evaluating black market and bootleg anabolic compounds that are produced illegally, and can be used for disqualification of performers from competition when appropriate.

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